

In re Application of  
David Sidransky  
U.S. Serial No.: 09/420,433  
Filed: October 12, 1999  
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PATENT  
Attorney Docket No.: JHU1180-1

## II. REMARKS

Upon entry of the present amendment, claims 1 to 4, 7 to 14, 18 to 22, and 24 to 26 will be pending.

### **A. Regarding the Amendments**

Claims 15 to 17, 23 and 27 are cancelled herein without disclaimer, and without prejudice to Applicant pursuing prosecution of subject matter encompassed within the claims as previously pending in an application claiming the benefit of priority of the subject application. It is submitted that the amendment does not require a new search or consideration, and places the application in condition for allowance, or in better condition for appeal. Accordingly, it is respectfully requested that the amendment be entered.

### **B. Rejections under 35 U.S.C. § 112**

The rejection of claims 1 to 4 and 7 to 27 under 35 U.S.C. § 112, second paragraph, as allegedly vague and indefinite is respectfully traversed.

It is stated in the Office Action that the claims are indefinite because it is unclear how claims 15 to 17, 23 and 27 further limit their independent base claims. It is stated, for example, that, in view of the recitation in claims 15 to 17, 23 and 27, it appears that the terms APC, DCC, NF1, etc., which are known tumor suppressor genes, are being given a meaning in the independent claims other than that known in the art.

Claims 15 to 17, 23 and 27 have been cancelled herein, and it is stated for the record that the terms "APC, DCC, NF1, NF2, RET, VHL and WT-1", as recited in the independent claims, are intended to have their well known meaning (i.e., as the respective known tumor suppressor genes). Accordingly, it is submitted that the amended claims are clear and definite and, therefore, respectfully requested that the rejection under 35 U.S.C. § 112, second paragraph, be removed.

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### **C. Prior Art Rejections**

The rejection of claims 1 to 4, 7 to 8, 10, 12, 14 to 16, 18 and 19 under 35 U.S.C. § 102(a) as allegedly anticipated by Nees et al. is respectfully traversed.

Nees et al. describe methods for detecting p53 mutations in tumor, tumor-adjacent tissue, and tumor-distant specimens of head and neck cancer patients, and that the tumor-adjacent and tumor-distant specimens did not exhibit a neoplastic morphology. Although it was argued in the previous Amendment that the claims as amended recite to specific mutant target nucleic acids and target neoplastic nucleic acids, none of which is p53, and pointed out that Nees et al. do not teach or suggest a target nucleic acid other than p53, it is alleged in the present Office Action that, based on the language of claims 15 and 16, for example, that the meaning attributed to the recited "tumor suppressor genes" could not be determined.

In view of the present amendments, and for the reasons set forth above, it is submitted that the claims recite specific tumor suppressor genes, not including p53, and maintained that Nees et al. only describe p53, but do not teach or suggest a target nucleic acid other than p53. Accordingly, it is submitted that the cited reference does not anticipate the claimed invention and, therefore, respectfully requested that the rejection of the claims under 35 U.S.C. § 102(a) as anticipated by Nees et al. be removed.

The rejection of claim 13 under 35 U.S.C. § 102(a) as allegedly anticipated by Nees et al. in view of Sobol et al. is respectfully traversed.

This rejection is maintained for similar reasons as set forth in the rejection based on Nees et al., alone (above). In view of the present amendments, and for the reasons set forth above, it is maintained that neither Nees et al. nor Sobol et al. teach or suggest a target nucleic acid other than p53 or, specifically, a tumor suppressor gene as recited in the claims. Accordingly, it is submitted that the cited reference does not anticipate the claimed invention and, therefore, respectfully requested that the rejection of the claims under 35 U.S.C. § 102(a) as anticipated by Nees et al. in view of Sobol et al. be removed.

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The rejection of claim 9 under 35 U.S.C. § 103(a) as allegedly obvious over Nees et al. in view of Watling et al. is respectfully traversed.

As above, the present rejection is maintained for similar reasons as set forth in the rejection based on Nees et al., alone (above). In view of the present amendments, and for the reasons set forth above, it is maintained that Nees et al., either alone or in combination with Watling et al., do not teach or suggest a target nucleic acid other than p53 or, specifically, a tumor suppressor gene as recited in the claims. Accordingly, it is submitted that the cited references would not have rendered the claimed methods obvious, and, therefore, respectfully requested that the rejection of claim 9 under 35 U.S.C. § 103(a) as obvious over Nees et al. in view of Watling et al. be removed.

The rejection of claim 11 under 35 U.S.C. § 103(a) as allegedly obvious over Nees et al. in view of Mullis et al. is respectfully traversed.

Again, the present rejection is maintained for similar reasons as set forth in the rejection based on Nees et al., alone (above). In view of the present amendments, and for the reasons set forth above, it is maintained that Nees et al., either alone or in combination with Mullis et al., do not teach or suggest a target nucleic acid other than p53 or, specifically, a tumor suppressor gene as recited in the claims. Accordingly, it is submitted that the cited references would not have rendered the claimed methods obvious, and, therefore, respectfully requested that the rejection of claim 11 under 35 U.S.C. § 103(a) as obvious over Nees et al. in view of Mullis et al. be removed.

The rejection of claims 20 to 27 under 35 U.S.C. § 103(a) as allegedly obvious over Nees et al. in view of Sobol et al. is respectfully traversed.

The present rejection is maintained for similar reasons as set forth in the rejection based on Nees et al., alone (above). In view of the present amendments, and for the reasons set forth

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above, it is maintained that Nees et al., either alone or in combination with Sobol et al., do not teach or suggest a target nucleic acid other than p53 or, specifically, a tumor suppressor gene as recited in the claims. Accordingly, it is submitted that the cited references would not have rendered the claimed methods obvious, and, therefore, respectfully requested that the rejection of the claims under 35 U.S.C. § 103(a) as obvious over Nees et al. in view of Sobol et al. be removed.

The rejection of claim 17 under 35 U.S.C. § 103(a) as allegedly obvious over Nees et al. in view of Knudson et al. is respectfully traversed.

The present rejection is maintained for similar reasons as set forth in the rejection based on Nees et al., alone (above). In view of the present amendments, and for the reasons set forth above, it is maintained that Nees et al., either alone or in combination with Knudson et al., do not teach or suggest a target nucleic acid other than p53 or, specifically, a tumor suppressor gene as recited in the claims. Accordingly, it is submitted that the cited references would not have rendered the claimed methods obvious, and, therefore, respectfully requested that the rejection of claim 17 under 35 U.S.C. § 103(a) as obvious over Nees et al. in view of Knudson et al. be removed.

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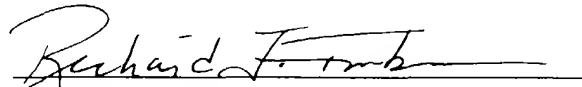
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In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to the subject application.

Please charge any additional fees, or made any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: May 5, 2003

  
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